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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,430

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Charli Kruse

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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

01/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 10/820,430	Applicant(s) KRUSE, CHARLI	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,5-14 and 48-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5-14 and 48-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/27/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant filed a response to the Non-Final Action of April 29, 2008 on October 27, 2008. A supplemental response was filed on October 31, 2008.

Claims 1, 2, 4, 15-47 are cancelled. Claim 10 is amended. As a reminder, with regard to the species election of site where acinar tissue is obtained, Applicant elected, without traverse, pancreas, as the site (Applicant's response, September 25, 2006).

Claims 3, 5-14, 48-61 are under consideration.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on October 27, 2008. The IDS has been considered.

Claim Objection

Claims 14, 48-50 are objected to. Per the species election of September 25, 2006, Applicant has elected pancreas (and acinar tissue of pancreas) as the species to be examined. Claim 14 has been examined, as indicated in the Office Actions of July 24, 2007 and December 15, 2006, with respect to the species election of pancreas. In the amendment of January 24, 2008, Applicant's amendment of claim 14 has eliminated "pancreas" as the elected species. Similarly, claims 48 and 49 are drawn to non-elected species. Claim 14 is objected to for eliminating the species of "pancreas" from the claim and claims 48-50 are objected to for being drawn to species of tissue that are

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not “pancreas.” As such, the species recited in claims 14, 48-50 are withdrawn from examination and the claims are being examined are readable on “pancreas.”

Withdrawn Rejections

35 USC § 102

Applicant’s arguments, see page 9 of Applicant’s response, filed October 27, 2008, with respect to the rejection of claims 10-13 as being anticipated by Schneider et al., 2001 have been fully considered and are persuasive. Applicant indicates that claim 10 has been amended to a culture “consisting” of the composition according to claim 3. The rejection of claims 10-13 has been withdrawn.

Applicant’s arguments, see pages 9-10 of Applicant’s response, filed October 27, 2008, with respect to the rejection of claims 10-13 as being anticipated by Apte et al., 1998 have been fully considered and are persuasive. Applicant indicates that claim 10 has been amended to a culture “consisting” of the composition according to claim 3. The rejection of claims 10-13 has been withdrawn.

Applicant’s arguments, see pages 10-12 of Applicant’s response, filed October 27, 2008, with respect to the rejection of claims 3, 5-13, 59, 60 as being anticipated by Roberts et al. have been fully considered and are persuasive. Applicant indicates that the specification, page 12, excludes tissue obtained from a human fetus. The rejection of claims 3, 5-13, 59, 60 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-14, 48-61 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record, April 29, 2008.

Applicant's arguments filed October 27, 2008 and October 31, 2008 have been fully considered but they are not persuasive.

With regard to the claims being drawn to pluripotent stem cells from any species of mammal (more specifically, pancreas, per the species election), the Examiner has limited the enablement to human and rat, given the guidance of Pera et al. (Office Action, April 29, 2008, pages 4-5). Applicant indicates that a declaration by Dr. Kruse will be submitted, including the evidence that pluripotent stem cells can be isolated from pancreatic tissue of a third species, goat (Applicant's response, October 27, 2008, page 8; October 31, 2008, page 4). In response, the declaration by Dr. Kruse is not persuasive because Dr. Kruse indicates that pluripotent stem cells were obtained from salivary gland from goat (Dr. Kruse's declaration, October 31, 2008), point 8. Salivary gland is not the same as pancreatic tissue and thus, an artisan cannot conclude that

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stem cells from the pancreas of any mammal are the same between different species of mammal. The rejection regarding this issue remains.

With regard to the issue regarding nestin being a stem cell marker, Applicant submits the Kajahn reference, wherein Kajahn et al., page 4, col. 2 indicates that nestin is an adult stem cell marker (Applicant's response, October 27, 2008, page 8). In response, as indicated in the Office Action, April 29, 2008, page 6, the Examiner has indicated that the art teaches that nestin is a stem cell marker and is not limited to the neural lineage. However, nestin is not an ES cell marker. Per NIH guidelines, ES cells express Oct-4 (Office Action, April 29, 2008, page 3), and nothing in the specification provides guidance that this protein was expressed. With regard to the citation of nestin, Kajahn et al. teach that nestin is a stem cell marker, however, it is noted that Kajahn et al. teach that the marker is indicative of a cell being an adult stem cell. As such, nestin is not indicative that the cells described in the specification are pluripotent, like that of ES cells. As such, the rejection regarding this issue remains.

With regard to the Office Action, April 29, 2008, page 3, indicating that the specification does not teach that the claimed cells have a normal karyotype, Applicant indicates that an independent laboratory in Kaiserslautern, German indicates that the cells have a normal karyotype (Applicant's response, October 31, 2008, page 4; see also declaration of Dr. Kruse, filed October 31, 2008, point 9). The rejection as it applies to this issue is withdrawn.

Thus, the claims remain rejected.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Primary Examiner
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